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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,951	11/01/2000	Alison Gillespie	SD9951IA	4050

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EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/703,951	GILLESPIE ET AL.	
	Examin r	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspond nc address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *7-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *081301* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election (10/31/02) of Group I, claims 1-6 is acknowledged. Claims 7-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. As no arguments were presented as to why the restriction requirement might be improper, the election is treated as being made **without** traverse; thus the restriction requirement is maintained and made FINAL.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

In the instant case, the invention of claims 1, 2, 4-6, i.e. a polynucleotide encoding an "α7 subunit of a human neuronal nicotinic acetylcholine receptor", does not appear to be supported in prior application 08149503. Support for such appears in prior application 08487596, filed 6/7/95; therefore claims 1, 2, 4-6 will be given the priority date of 6/7/95.

Additionally the invention of claim 3, i.e. a cell line derived from a rat pituitary tumor, does not appear to be supported by any prior application. Thus, the priority date for claim 3 is given to be the filing date of the instant application.

Claim Objections

Claim 4 is objected to because of the following informalities: Claim 4 has the following typographical error: heterologou sprotein. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the following reasons.

Claims 1-4 recite the term "α7 subunit of a human neuronal nicotinic acetylcholine receptor". The recited term "α7 subunit of a human neuronal nicotinic acetylcholine receptor", without reference to a specific sequence identifier, is indefinite because the instant specification does not identify that material element or combination of elements which is unique to, and therefore, definitive of an"α7 subunit of a human neuronal nicotinic acetylcholine receptor". An artisan cannot determine what limitations are placed upon a claim by the presence of this term.

Claim 1 recites the term "suitable host cell", yet neither the specification nor the claim set forth what the host cell is to be suitable for, thus the bounds of the claim cannot be determined.

In claims 4 and 5, the phrase "the heterologous protein" lacks antecedent basis in the claims; thus the artisan cannot know which heterologous protein is "the heterologous protein". Likewise, the term "the heterologous nucleic acid" lacks antecedent basis in claim 6.

Similarly "the cell line according to claim 1" lacks antecedent basis in claims 3-6.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding the α7 subunit of a human neuronal nicotinic acetylcholine receptor having the amino acid sequence set forth in SEQ ID NO: 8, does not reasonably provide enablement for polynucleotide that encode an α7 subunit of a human neuronal nicotinic acetylcholine receptor having an amino acid sequence other than that of SEQ ID NO: 8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

At the outset, it is noted that the claims are interpreted to be limited to polynucleotides encoding a protein having an amino acid sequence known to be present in a human being, otherwise the protein would not be considered to be a human neuronal nicotinic acetylcholine receptor, as is required by the claims. While one of skill in the art would accept with virtual certainty that there must exist in the human population amino acid sequence variants of the polypeptide of SEQ ID NO: 8 (as encompassed by the claims), perhaps many, the specification has not taught where to find such variants. Instead, with the specification as a guide, the skilled artisan is simply left to undergo an extensive research effort, wherein the genes encoding SEQ ID NO: 8 are sampled from among the human population in the hope of finding variants. Because the specification has not taught where to look for these variants, e.g. that a variant might

correlate with a particular disorder or other phenotype, this research effort would be essentially random. One skilled in the art would certainly consider such random trial and error experimentation to be unduly burdensome.

The claims are, in essence, single means claims, because the claims encompass any composition having the recited activities whereas the instant specification only discloses one such composition known to the inventor. In *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), a single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification at most disclosed only those means known to the inventors. When claims depend on a recited property, a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See also *Fiers v. Sugano*, 984 F.2d 164, 25 USPQ2d 1601 (Fed. Cir. 1993), and MPEP § 2164.08(a). With regard to enablement for variants of the polypeptides encoded by SEQ ID NO: 7, having the property that they must be present in a human being, the instant fact pattern is similar to that of *Hyatt*.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses an α7 subunit of a human neuronal nicotinic acetylcholine receptor polypeptide and an α7 subunit of a human neuronal nicotinic acetylcholine receptor

polynucleotide of SEQ ID NO: 8 and 7, respectively, yet the claims encompass polynucleotides not described in the specification, i.e. polynucleotides sequences of allelic variant or splice variants, or sequences need that need only hybridize to SEQ ID NO: 7 under stringent conditions yet which retain the required property of being human. None of these sequences meet the written description provision of 35 U.S.C. 112, first paragraph. Although one of skill in the art would reasonably predict that these sequences exist, one would not be able make useful predictions as to the nucleotide positions or identities of those sequences based on the information disclosed in the specification.

The instant disclosure of a single polynucleotide, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, a single human polynucleotide sequence, which is not sufficient to describe the essentially limitless genera encompassed by the claims.

With the exception of polynucleotides encoding an α7 subunit of a human neuronal nicotinic acetylcholine receptor having amino acid sequence of SEQ ID NO: 8, the skilled artisan cannot envision the detailed chemical structure of the encompassed "α7 subunit of a human neuronal nicotinic acetylcholine receptor" that are not identical to SEQ ID NO: 8, therefore

conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only polynucleotides encoding SEQ ID NO: 8, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Peng-X et al., Molecular Pharmacology 45(546-554)1994.

Peng-X et al. disclose a host cell transfected with an isolated nucleic acid molecule comprising a sequence of nucleotides that encodes α7 subunit of a human neuronal nicotinic acetylcholine receptor, wherein the vector is an expression vector, and wherein the heterologous protein is a functional neuronal nicotinic acetylcholine receptor, see col 2 of page 547.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peng-X et al., Molecular Pharmacology 45(546-554)1994 in view of Sambrook-J. ed. Molecular Cloning, Cold Spring Harbor Laboratory Press, 1989, pgs 16.3-16.21. Claim 2 requires that the receptor be inducibly expressed and claim 5 requires a selectable marker gene. Peng-X et al. did not use such in their experiments but to do so is well established, old, and routine in the art of the molecular characterization of proteins as reviewed and taught by Sambrook, e.g. see pages 16.9 and 16.20, as a matter of routine optimization of operating parameters. Therefore, one of ordinary skill in the art, at the time the invention was made, and with reasonable expectation of success, would be motivated to use selectable markers and/or inducible promoters as taught by Sambrook when characterizing the protein of Peng-X et al, as a matter of routine optimization of operating parameters, as reviewed by Sambrook.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peng-X et al., Molecular Pharmacology 45(546-554)1994 in view of Quik-M et al. Journal of Neurochemistry 67(145-154)1996. Claim 3 requires that the cell line be a rat pituitary cell line. Quik et al. teach that the α7 subunit of a neuronal nicotinic acetylcholine receptor should be expressed in rat pituitary cell line because these cells do not possess natural nicotinic acetylcholine receptors and thus the expressed α7 subunit can be studied without interference from endogenous receptors (see the Abstract). Therefore, one of ordinary skill in the art, at the time the invention was made, and with reasonable expectation of success, would be motivated to express the α7 subunit encoding nucleic acid of Peng-X et al. in a rat pituitary cell line as taught by Quik. The motivation to do so is provided by Quik who teach the desirability of doing so, as explained above.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564 until January 22, 2003 and at (571) 272-0871 thereafter.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

MB

January 22, 2004